REMARKS

In the March 24, 2010 Office Action, claims 1-5, 8, 9, 11-13, 15-17, 20-25, 27, 29, 37, 40, 41, 43, 44 and 46-48 are rejected under 35 U.S.C. §103 from Aoyama U.S. Patent No. 6,827,963 in view of Wester U.S. Patent No. 6,589,588, C.F.R. §101.83 and St.-Onge *et al.* "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride Oil Improves Plasma Profiles in Men," taken together, as further evidenced by Bailey pages 192-196 and 210-212.

The Invention

Independent claim 1 is directed to a liquid vegetable oil composition, independent claim 37 is directed to a method for making a health and nutrition promoting liquid vegetable oil composition, and independent claim 40 is directed to a method for using a medium chain triglyceride in a health and nutrition promoting liquid oil composition. Each of independent claims 1, 37 and 40 is amended to recite that the randomization reaction product and method involve a randomization interesterification catalyst, and new claims 49-51 list specific such catalysts. Support is found, for example, in paragraphs [0029] and [0030]. The three independent claims each specify, among other Features:

A. An interesterified liquid lipid component that is an all-vegetable component. Independent claims 1 and 37 state that this component comprises at least 88 weight percent of the composition.

B. The interesterified lipid component is a randomization reaction product of a reactant charge and a randomization interesterification catalyst, the product having interexchanged first and second fatty acid moiety chains that vary randomly from glycerol structure to glycerol structure.

C. The first fatty acid moiety chains are of medium chain triglycerides of caprylic triglyceride, capric triglyceride or combinations thereof.

D. The second fatty acid moiety chains are long chain (at least C16) domestic vegetable oil triglycerides of soybean oil, corn oil, cottonseed oil, canola oil, olive oil, peanut oil, safflower oil, sunflower oil, oil from grain plants, and combinations thereof.

E. A phytosterol ester component is included in the composition at 2 to 12 weight percent, as specified in claims 1 and 40, or at 2 to 10 weight percent according to claim 37.

F. The composition reduces cholesterol adsorption in individuals (claim 1); consumption of the composition reduces LDL cholesterol adsorption by an individual (claim 37); and administering the composition to an individual to reduce LDL cholesterol adsorption by the individual (claim 40).

Feature F is directed to the health and nutrition promoting characteristics of applicants' claimed invention. The liquid lipid component according to the invention,for example, the combination of Features A through D, when included as the major component of the claimed composition and methods (incorporating the phytosterol ester component as in Feature E) bring about **enhanced phytosterol delivery**, as illustrated in Example 15, paragraphs [0098] to [0102]. Applicants' invention is discussed in Rudkowska *et al.* published in 2006 as an Elsivier distribution, which is of record in the application, having been submitted with the Amendment of September 18, 2008 as non-prior art, provides test data illustrating health promotion in terms of increased reducing cholesterol adsorption in individuals.

The Obviousness Rejection

Under 35 U.S.C. §103(a), the initial burden is on the Office to produce evidence that the claimed invention is *prima facie* obvious. To establish a *prima facie* case of obviousness, all of the claim limitations must be taught by the cited art, in such combination each element merely performs the same function as it does separately, one of ordinary skill would have recognized that the results from the combination were predictable, and whatever additional findings may be necessary to explain a conclusion of obviousness. MPEP §2143, section A(1). The references of the present rejection do not teach or suggest all the limitations of applicants' claims. Therefore, no *prima facie* case of obviousness has been established, and arguments and test data rebut same.

Page 3 of the Office Action acknowledges that Aoyama teaches directed interesterification to prepare triglycerides, such being recognized as being the case in all of the Aoyama examples and as reported in Aoyama. The Office Action references lines 18-23 in column 8 of Aoyama, stating: "The use of random or chemical interesterification is suggested."

Page 3 also takes the position that the specific way applicants' synthesized triglyceride is made is a process limitation, carrying no weight in product claim 1. Applicants respectfully observe that claim 1 does recite its liquid lipid component in terms of chemical structure and not as only a process limitation. More specifically, claim 1 recites specific medium chain vegetable triglycerides, defining same as having first fatty acid moiety chains. Similarly, claim 1 specifically recites a selection of long chain domestic vegetable oils, defining them as having second fatty acid moiety chains of at least C16 in length. The specific medium chain triglycerides specified in claim 1 are much shorter in chain length, namely caprylic, which is C8, and capric, which is C10. Thus, claim 1 specifies first fatty acid moiety chains having a chain length different from (substantially less than) the second fatty acid moiety chains. Furthermore, the liquid lipid component is further identified in structural or product terms as being a randomization reaction product having interchanged first and second fatty chains that vary randomly from glycerol structure to glycerol structure. In other words,

while the liquid lipid component is referred to in claim 1 as a randomization reaction product, this product is also defined in product terms, namely having first and second (*i.e.*, different) fatty acid moiety chains that define the liquid lipid component as having those different first and second chains on the glycerol structure in a random fashion.

Because of the nature of randomness, it is not possible to provide a specific structural formula, such as the Formulas of Aoyama. As noted elsewhere by applicants, this is a very important point of distinction between Aoyama, which is able to provide specific structural Formulas for the directed interesterification products described in Aoyama. Instead of such formulations, applicants claim the liquid lipid component as having randomly distributed on each glycerol structure the specifically defined first or second fatty acid chains.

Aoyama Neither Discloses Nor is Predictive of the Invention:

Aoyama does not disclose or teach the applicants' liquid lipid component. Instead, Aoyama teaches driving the esterification to triglycerides in which specified fatty acids are combined so as to provide a specific acyl group at the first portion, a specific acyl group at the second portion and a specific acyl group at a third portion of the triglyceride molecule. Same are disclosed by Aoyama as "Formulas," namely Formula I, Formula II, Formula II', Formula III, Formula III', Formula IV, Formula V or Formula VI.

Despite the fact that Aoyama does not teach Feature B, applicants understand the Office's reliance on the statement at lines 19-23 in column 8 of Aoyama "contemplates random interesterification" means that the Office is arguing that Aoyama intrinsically discloses triglycerides prepared by random interesterification where first and second (*i.e.*, different) fatty acid chains vary randomly from glycerol structure to glycerol structure.

Applicants appreciate that lines 20-21 in column 8 of Aoyama recite the phrase "a chemical synthesis method." The Office apparently agrees this is the one and only time Aoyama provides any disclosure or alleged teaching about "chemical synthesis" or randomization reaction products. It is of course very

evident from Aoyama that any degree of Aoyama enablement or disclosure for ester preparation concerns only **the enzyme method** to prepare the **Aoyama fats and oils composition**. In addition to the phrase "a chemical synthesis method," this paragraph in column 8 of Aoyama also mentions "a method of extracting from natural fats and oils" as well as "a genetic recombination method of oil seeds." As with the "chemical synthesis" method, Aoyama provides no disclosure concerning these other two methods, other than to name them.

Applicants understand the Office agrees that the secondary references to Wester, C.F.R. St.-Onge and Bailey do not concern interesterification; accordingly, the focus of the present prosecution concerns what one of ordinary skill in the art would have been taught by Aoyama without the benefit of applicants' disclosure and teaching. The one-time mention of "a chemical synthesis method" in column 8 of Aoyama would not have taught one of ordinary skill in the art to expect formation of applicants' invention. Aoyama teaches making only **Aoyama** compositions irrespective of the method. In other words, Aoyama is not "predictive" of applicants' invention as required for obviousness.

Aoyama Does Not Enable the Invention:

Furthermore, Aoyama does not enable one of ordinary skill in the art to achieve applicants' claimed invention. Applicants note that M.P.E.P. §2145 states:

> A conclusion of obviousness requires that the reference(s) relied upon be **enabling in that it put the public in possession of the claimed invention**. (citing *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968), bolding added.)

Aoyama's teachings and disclosure regarding using the enzyme method to drive the esterification toward the Aoyama compositions that Aoyama identifies as triglycerides of specific structures, namely the Formulas noted above, does not intrinsically result in or otherwise enable the interesterified randomization liquid structured lipid component of applicants' claims.

From the Examiner's Answer in the now-withdrawn appeal, applicants understand the Office to concede that Aoyama **itself** is not enabling for using "a chemical synthesis method" to make applicants' products or to teach applicants' methods. Pages 8 and 12 of the Examiner's Answer notes applicants' disclosure of chemical interesterification at page 4, paragraph 7 and argues the four patents identified there by applicants satisfies the enablement shortcoming for Aoyama. Applicants respectfully disagree.

First, Aoyama itself does not suggest or state or incorporate anything by reference to enable its "a chemical synthesis method" phrase.

Second, the four patents to which applicants refer in their specification do not enable randomization interesterification of the triglycerides of applicants' claims. Applicants provide the disclosure that allows same, using the four patents as a starting point.

Third, Aoyama teaches different products. Applicants appreciate the Examiner's Answer states at page 8: "The Examiner does not believe that the structural formulas of Aoyama and the claims are different." Applicant respectfully disagrees. After all, Formulas I through VI are the structures that Aoyama teaches its reaction needs to be driven to. What Aoyama teaches it does **not** want is a situation where there is no direction (*i.e.,* there is randomization). Aoyama teaches away from randomization interesterification allowing different fatty acid moiety groups to land where they may. Accordingly, Aoyama is not enabling of applicants' structured lipid because it enables only its Formulas I through VI.

Fourth, enablement of enzyme interesterification does not enable "a chemical synthesis method." This is because enzymes and randomization interesterification catalysts are very different from each other and would require much more than the simple statement "a chemical synthesis method" in order to intrinsically teach or enable preparation of a different product (applicants' claimed invention versus Aoyama's Formulas) by a different means ("a chemical synthesis method" versus "the enzyme method"). Each reacts with substrates at different rates and with different selectivities based on many characteristics such

as shape, size and electrostatic interactions. For example, enzyme catalysts of enzyme syntheses are relatively complex large chemical structures, while chemical catalysts of chemical syntheses are of a relatively small and simple chemical structure. Note, for example, the randomization interesterification catalysts of new claims 49-51. The skilled artisan would need details of interesterification conditions, such as whether the chemical synthesis conditions are under an acidic or a basic condition. Of course, any such disclosure is absent from Aoyama.

Summary Regarding Aoyama:

In summary, applicants urge reconsideration because of these important shortcomings of Aoyama:

1. Aoyama does not teach, enable or render predictive to the skilled esterification artisan how to make, by "a chemical synthesis method," either the Aoyama "fats and oils composition" Formulas or applicants' claimed liquid lipids.

2. To the extent the skilled esterification artisan would be taught anything by Aoyama by the stand-alone phrase "a chemical synthesis method" the teaching would be that Aoyama teaches driving interesterification to or toward the Aoyama Formulas and teaches away from non-driven randomization as applicants claim.

3. The esterification artisan would not be enabled to achieve random interexchanging through interesterification by the simple statement in Aoyama of "a chemical synthesis method" inasmuch as Aoyama itself is devoid of any mention – let alone any specifics – of interesterification conditions for "a chemical synthesis method."

The Secondary References

Concerning the secondary references, the paragraph common to pages 5 and 6 of the Office Action acknowledges that none of Wester, C.F.I., St.-Onge or Bailey are directed to random interesterification. Applicants understand the

Office does not dispute that neither St.-Onge nor the other secondary references teach an MCT having undergone interesterification with a long chain domestic oil.

St.-Onge mentions **blends** of medium chain triglyceride oil and phytosterols, without any suggestion that an MCT oil according to St.-Onge would have been or is to be interesterified – randomly or otherwise – with any other component, let alone with a long chain domestic oil as applicants claim. For example, the Abstract of St.-Onge states that the study of that publication evaluates the effects of a combination of MCT oil, phytosterols and flaxseed oil ("functional oil" or FctO) on plasma lipid concentrations and LDL particle size. The first paragraph of St.-Onge refers to medium chain triglycerides (MCT) and the effects thereof. Throughout St.-Onge, the reference is to "MCT" or "MCT oil." In the second paragraph on page 1816, St.-Onge reports that the dietary fat of the testing reported by this article was either "FctO or OL." The next paragraph states that FctO "was prepared by heating MCT oil and coconut oil and dissolving tall oil phytosterols ..." A footnote identifies FctO as functional oil and OL as olive oil. Thus, the facts of St.-Onge are either olive oil or a blend of MCT oil and another oil, such as flaxseed oil or coconut oil. Neither FctO nor OL is an interesterified structured lipid of applicants' claims. Table I of St.-Onge provides further information about the FctO diets. Only MCT oil, cocoanut oil, canola oil and flaxseed oil are listed, no interesterified products being listed. Similarly, Table II shows the makeup of fatty acids in the FctO, again providing no suggestion that these concern anything but blends of fatty acid oil. The first paragraph of the Discussion section that begins on page 1818 of St.-Onge, in the very first sentence, refers to "a combination of MCT oil, phytosterols and flaxseed oil." Again, nothing about interesterification, random interesterification or esterification of any type. The very last sentence in this Discussion section of St.-Onge specifically refers to "an MCT-containing oil blend." **A blend is not an interesterification**.

The **St.-Onge** reference also is cited for its teaching that oils rich in phytosterols and medium chain triglyceride oil are known to be improved by plasma lipid profiles. St.-Onge does not remove Aoyama's or Wester's or the

C.F.R.'s deficiencies regarding the claimed randomized interesterified liquid lipids inventions claimed by applicants.

The Office relies upon **Wester** to address Aoyama's failure to disclose phytosterol esters. Wester is cited as teaching incorporation of phytosterol esters into specific foods including cooking oils to reduce serum cholesterol in the body by reducing the absorption of cholesterol from the digestive tract. Applicants do not claim phytosterols or their use as their invention. But applicants claim their composition of the claimed liquid structured lipid randomization interesterification component combined with the phytosterol ester component improves phytosterol delivery and reduces cholesterol adsorption in individuals. Because Wester has no teaching concerning random interesterification or the liquid structured lipid components that are claimed by applicants and that are not taught or contemplated by Aoyama, Wester does not remove Aoyama's extensive deficiencies.

The Office relies on the **C.F.R.** reference for showing levels of phytosterol ester fortification required to make labeling claims with regard to lowering cholesterol and reducing coronary heart disease risk. This reference has no teaching concerning randomization interesterification or with applicants' claimed liquid lipid component having the randomly positioned first and second fatty acid chains or moieties.

Bailey is relied upon with respect to properties of viscosity and smoke point and melting points of certain vegetable oils, not randomization interesterification lipids of the invention. Nor does Bailey teach any of these properties for interesterification products from any such vegetable oils.

For these reasons, the combination of Aoyama plus these references – even if they had been obvious to combine – would not have led one of ordinary skill to all of Features A through F. Reconsideration and withdrawal of the §103 rejection are respectfully requested with respect to these claims.

Features Other Than Features A-F

Concerning claims 15 and 47, neither Aoyama nor any of the secondary references would have obviously led to a liquid lipid composition that is a clear liquid and remains a clear liquid for at least six months when stored at 21°C. Table I, Table II and paragraphs [0056] to [0064] of the present application report tests that illustrate this feature, including oxidative stability being twice that of fresh canola oil. These data and paragraphs show the advantages of this feature of claims 15 and 47 by having an edible oil composition remain stable and clear (paragraph [0057]) much longer than control oils such as canola oil.

Claims 16 and 48 are directed to the feature that the oil composition has sensory attributes not significantly different from or significantly superior to corresponding sensory properties of canola oils that do not have a phytosterol component. This feature means that the phytosterol sensory properties are "masked," being at least as good as a premium edible oil, namely canola oil, that does not have any phytosterol blended into it. This feature is reported on and discussed in greater detail in multiple locations in the application as filed, including paragraphs [0055] and [0056], as well as Table I of Example 1, and especially at paragraphs [0069], [0071], [0073], [0075], [0079] and [0082]. Test results included in these passages establish this sensory feature improvement over canola oils known in the industry for their high-end attributes.

References such as Wester, C.F.R. and St.-Onge do not disclose that any of the edible oils discussed therein have this important sensory feature in relation to phytosterols. It would not have been obvious to modify these references by replacing edible oils, including those mentioned in St.-Onge, for example, with the liquid lipid component of applicants' invention.

Claims 17 and 48 are directed to the feature that the oil composition has sensory attributes not significantly different from or significantly superior to corresponding sensory properties of olive oils that do not have a phytosterol component. This feature means that the phytosterol sensory properties are "masked," being at least as good as a premium edible oil, namely olive oil, that does not have any phytosterol blended into it. This feature is reported on and

discussed in greater detail in multiple locations in the application as filed, including paragraphs [0075] and [0084], as well as Table III of Example 1. Test results included in these passages establish this sensory feature improvement over olive oils known in the industry for their high-end attributes.

References such as Wester, C.F.R. and St.-Onge do not disclose that any of the edible oils discussed therein have this important sensory feature in relation to phytosterols. It would not have been obvious to modify these references by replacing edible oils, including those mentioned in St.-Onge, for example, with the liquid lipid component of applicants' invention.

Independent claim 37 is directed to a method for making a health and nutrition promoting liquid vegetable oil composition. Thus, claim 37 has the specific features of introducing the reactants that are specifically identified in claim 37 and interesterifying these reactants by randomization with a randomization interesterification catalyst that interchanges fatty acid moieties to the interesterified liquid lipid component having interchanged first and second fatty acid moiety chains that vary randomly from glycerol structure to glycerol structure. Because the Office has not taken the position that these features are to be given no weight in claim 37, any concern about the inapplicability of such method step features is obviated by the fact that claim 37 is a method claim.

Independent claim 40 is directed to a method for using a medium chain triglyceride in health and nutrition promoting liquid oil compositions. As with claim 37, claim 40 includes specific method steps, one being interesterifying by randomization that interchanges fatty acid moieties and so forth. Because claim 40 is a method of using, this includes an administering step that is not found in claim 1 or claim 37. This administering step includes reducing LDL cholesterol adsorption by the individual to whom the composition is administered.

Applicants respectfully point to data in the application and in a publication of testing under applicants' invention (Rudkowska *et al.*) that show the unobvious and unexpected important advantages obtained when all of Features A, B, C, D, E and F are present. Page 6 of the Office Action states there is no unobvious difference seen between the test results of applicants and the test results of St.-

Onge. To the contrary, there is **an enhancement of half again the LDL cholesterol reduction** in applicants' data when compared with the St.-Onge data.

Applicants' claimed invention achieves an enhanced unexpected benefit when one compares the St.-Onge clinical study data with clinical testing using applicants' invention. This St.-Onge article reports data on reduction in LDL cholesterol of 14% when compared to the baseline. Data of the clinical study using applicants' claimed invention (2006 publication of Rudkowska *et al.* "Phytosterols Mixed with Medium-chain Triglycerides and High-oleic Canola Oil Decrease Plasma Lips in Overweight Men," which applicants had filed in this application (and is in the Evidence Appendix) show a reduction in LDL cholesterol of 21% when compared with the baseline.

More particularly, the respective clinical studies are properly compared due to similarities in testing protocol. The 2006 Rudkowska publication (applicants' claimed composition and methods) and the 2003 St.-Onge prior art relied upon each report on clinical testing of men having a body mass index of 25-31 kg/m^2. Twenty-three of these men completed the study using applicants' invention, while thirty men were in the study of the 2003 St.-Onge publication. Each study followed a randomized crossover type of test, and eachdelivered the phytosterol-containing component with the same isoenergetic meal protocol of 15% protein, 40% fat and 45% carbohydrates. In the 2006 clinical study according to applicants' claimed invention, blood samples were taken at days 1, 2, 41 and 42, whereas in the 2003 St.-Onge clinical study, blood samples were taken at days 1, 28 and 29. Each analyzed the blood samples and calculated LDL cholesterol using the Friedenwald formula.

The baseline LDL for applicants' invention was 3.59, same being reduced to the end point value of 3.12, **a reduction of 21%**. *See* data in thet able on page 393 in the "Functional Oil" columns and the "LDL-C" rows. As reported in Table 3 on page 1817 of the St.-Onge publication, the baseline for the functional oil (FctO) for LDL-C was 3.43, and the Endpoint was 2.96, **a reduction of 14%**. Thus, **there is a 7% greater baseline reduction with applicants' invention**

when compared with St.-Onge. This is an enhancement of **half again the enhancement** reported for St. Onge.

The combination of references does not provide significant predictability of this magnitude of enhanced effectiveness when the randomization interesterification products of the present claims are combined with phytosterols. The art provides no predictability that the randomly interesterified lipids would deliver the phytosterols with the enhanced effectiveness evident by these data.

Accordingly, these data provide further strong support for the unobviousness of the presently claimed invention. Reconsideration and withdrawal of the §103 rejection is believed to be in order for this additional reason.

Applicants have made an earnest endeavor to place this application into condition for allowance, and favorable consideration is respectfully requested.

Respectfully submitted

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